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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,816	10/02/2003	Dwight Jerome Holter		9791

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Dwight Holter  
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EXAMINER

BOGART, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/677,816	<b>Applicant(s)</b> HOLTER, DWIGHT JEROME	
	<b>Examiner</b> Michael G. Bogart	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-9 is/are allowed.
- 6) ☒ Claim(s) 10, 12, 17 and 18 is/are rejected.
- 7) ☒ Claim(s) 11 and 13-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Withdrawal of Allowable Subject Matter***

The indicated allowability of claims 17 and 18 is withdrawn in view of the newly discovered reference(s) to Moller (US 4,579,658). Rejections based on the newly cited reference(s) follow.

### ***Claim Objections***

Claim 15 is objected to because of the following informalities: Claim 15 recites the limitation "said closure means" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

### ***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

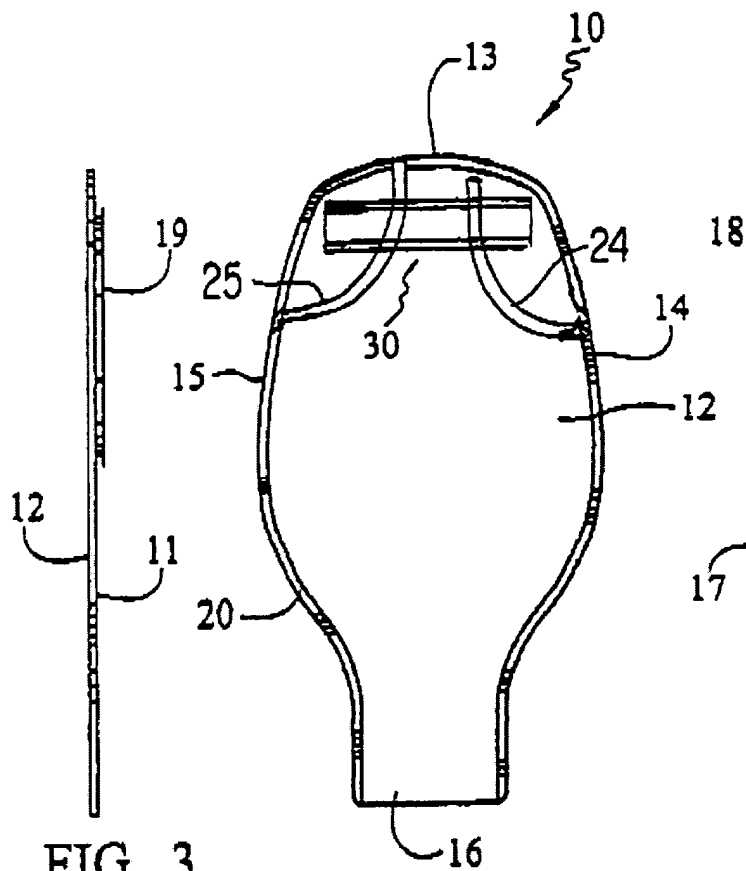
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Holtermann *et al.* (US 6,328,719 B1).

Regarding claim 10, Holtermann *et al.* teach an ostomy bag (10) comprising: (A) a main bag chamber (11, 12) having an upper extremity; (B) a multipurpose latent (hidden) tube (30)

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with said main bag chamber (11, 12), said latent tube (30) having a proximal end (34) attached to and opening to said main bag chamber (11, 12) upper extremity and providing the capability for fluid communication with said upper extremity, said tube (30) also having; (1) a distal end (35); and (2) significant latent tube length between said proximal end and said distal end; at least a substantial part of said length being parallel to and separably attached to said main bag chamber (11, 12)(see fig. 2, below).

FIG. 3FIG. 2

Holtermann *et al.* do not expressly disclose that the tube and ostomy bag are co-formed.

As interpreted herein, this means that the ostomy bag and tube of the instant invention are

formed simultaneously as opposed to separately and then later attached together. This limitation makes the claim a product-by-process claim.

Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)(citations omitted)(Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). MPEP § 2113.

Regarding the limitation of the instant invention that the tube is separable from the ostomy bag, one taking apart the bag could separate the tube from the bag.

Regarding claim 12, Holtermann *et al.* teach that said distal end is capable of providing axial gas flow out of said tube.

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Moller (US 4,579,658).

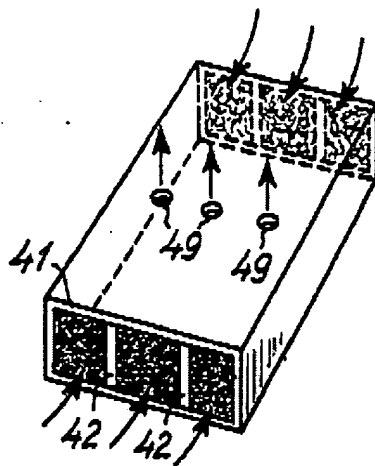
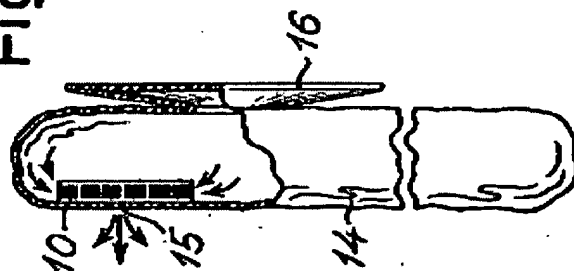
Regarding claim, 17, Moller teaches a stomal waste management system comprising multiple use latent tubing (41) having: (a) front and back walls comprising thin, flexible, water impermeable plastic, said latent tubing (41) further having at least one channel having a flat width dimension and at least two end openings, at least one of said openings being a proximal end through which gas can enter said tube, which latent tubing (41) takes tubular form as necessary for gas flow therethrough, and wherein said latent tubing (41) has at least one pair of spaced apertures (49) in one of its walls to accommodate attachment of a filter (37) with appropriately mating apertures (interstices in the filter web), said latent tubing (41) further having at least one interval seal (14) to route gas into said filter (37)(see figs. 3 and 10, below).

Moller does not teach the specific width dimension of the instant invention.

Mere changes in size are not sufficient to patentably distinguish a claimed invention over the prior art. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform

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differently than the prior art device, the claimed device was not patentably distinct from the prior art device. MPEP § 2144.04.

**Fig. 3.**

Regarding claim 18, Moller does not expressly disclose a plurality of pairs of apertures. Merely modifying the range of numbers of an element is not sufficient to patentably distinguish an invention over the prior art. MPEP § 2144.04.

***Allowable Subject Matter***

Claims 1-9 are allowed.

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Claims 11, 13 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 15 is objected to for the reasons described in detail supra.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 1-9, the art of record fails to teach or suggest an ostomy bag having a proximal end of a latent tube attached to its upper end wall or seal, the tube having a length to an opposite distal end allowing gas to flow therethrough, the tube having two seals or walls, the tube's seals or walls are separated from the upper seal or wall of the ostomy bag except at the point of attachment at the proximal end of the tube, one of the tubes seals or walls being near the ostomy bag's upper seal or wall, the other of the tube's seal or wall being further away from the upper seal or wall of the ostomy bag than the first wall of the tube.

Regarding claim 15, the art of record fails to teach or suggest the closure means which includes a blank having a slit, the slit not being in communication with the bag's main chamber or the tube.

Regarding claims 11, 13 and 14, the most relevant art of record, Holtermann *et al.* fail to teach that a large portion of the tube is not attached along its length to the ostomy bag, or a closure means for the tube.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.



In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart  
20 January 2006

**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**

